K122873

JAN 15 2013

510(k) Summary

5.1 **Type of Submission:** Traditional/Special/Abbreviated

5.2 **Preparation Date:** Sep 11, 2012

5.3 **Revised Date:**

5.4 **Submitter:** Caremed Supply Inc.

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Contact: TSUNG-HSUAN LIU

Establishment Registration Number: 8022590

5.5 **Identification of the Device:**

Proprietary/Trade name:	VASOPOUSE® Deep Vein Thrombosis Compression Device Model Name: IPCS/SQS Model No.: M6-9/M6-5
Common Name:	Compression Therapy Device
Classification Name:	Sleeve, Limb, Compression
Device Classification:	Class II
Regulation Number:	870.5800
Panel:	Cardiovascular
Product Code:	JOW

5.6 **Identification of the Predicate Device:**

Predicate Device Name:	VESOFLOW
Manufacturer:	CAREMED SUPPLY INC.
Product Code:	JOW
510(k) Number:	K110977

5.7 Intended Use and Indications for Use of the subject device

The Caremed Supply Inc. VASOPOUSE® SQS and IPCS Deep Vein Thrombosis (DVT) Compression Devices are intended to increase venous blood flow in at risk patients in order to help prevent deep vein thrombosis.

5.8 Device Description

VASOPOUSE® that counteracts blood stasis and coagulation changes – two of the three major factors that promote deep vein thrombosis (DVT) - a potentially life threatening condition which can lead to pulmonary embolism. VASOPOUSE® is a non-invasive mechanical prophylactic system that massages the legs in a wavelike, milking motion that promotes blood flow and deters thrombosis, helping to empty pooled or static blood from the valve cusps of the femoral vein. Fibrinolytic activity is increased, stimulating the release of a plasminogen activator. This therapy typically complements other prophylactic measures, such as ant embolic stockings and anticoagulants.

VASOPOUSE® is used to prevent pooling of blood in a limb by inflating periodically a sleeve around the limb. Therefore, VASOPOUSE® is identified as a compressible limb sleeve.

5.9 Statement of Substantial Equivalence

The VASOPOUSE® SQS and IPCS Deep Vein Thrombosis (DVT) Compression Devices are substantially equivalent in all aspects, e.g., technological characteristics, modes of operation, performance characteristics, intended use, etc., to the commercially available VESOFLOW SQS and IPCS DVT Compression Devices. The changes between the two systems include the exclusion of battery back up and the dimension of the pump.

5.10 Non-clinical Testing

A series of safety tests were performed to assess the safety and effectiveness of VASOPOUSE®. The safety tests were conducted in accordance with **EN/IEC60601-1-2:2007, ISO10993-1:2009, ISO10993-5:2009, and ISO10993-10:2002/AMD.1:2006(E)**. The performance testing conducted on subject device and predicate device are listed below:

- Function Test
- Vibration Test

- Shock Test
- Free Fall Drop
- Life Test

All the test results demonstrate VASOPOUSE® meets the requirements of its pre-defined acceptance criteria and intended uses.

5.11 Substantial Equivalence Determination

The VASOPOUSE® submitted in this 510(k) file is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the cleared VESOFLOW (K110977). Differences between the devices cited in this section do not raise any new issues of safety or effectiveness.

Item	VESOPOUSE®	VESOFLOW (K110977)
Similarities		
Regulation Number	870.5800	870.5800
Classification	Class II	Class II
Product Code	JOW	JOW
Prescription Use	Yes	Yes
Indications for Use	The Caremed Supply Inc. VASOPOUSE® SQS and IPCS Deep Vein Thrombosis (DVT) Compression Devices are intended to increase venous blood flow in at risk patients in order to help prevent deep vein thrombosis.	The Caremed Supply Inc. Vesoflow SQS and IPCS Deep Vein Thrombosis (DVT) Compression Devices are intended to increase venous blood flow in at risk patients in order to help prevent deep vein thrombosis.
Model	SQS/IPCS	SQS/IPCS
Pressure Range	Same	40/45 and 130 mmHg
Sterilization	N/A	N/A
Referenced Standards	Same	IEC60601-1: 1988+A1:1991+A2:1995 EN/IEC60601-1-2:2007 EN/IEC60601-1-4

		IEC60068-2-06 IEC60068-2-27 ISO14971:2007 ISO10993-1:2009 ISO10993-5:2009 ISO10993-10:2002/AMD.1:2006(E)
Differences		
Battery Pack	No	Yes

5.12 Conclusion

After analyzing bench tests, safety testing data, it can be concluded that VASOPOUSE® IPCS and SQS DVT Compression Device are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 15 2013

Caremed Supply Inc.
c/o Mr. Michael Lee
Consultant
7F., No. 2, LANE 235, BAO CHIAO RD.
NEW TAIPEI CITY, XIN TIEN DIST.
TAIWAN, R.O.C, 23145

Re: K122873
Trade/Device Names: VASOPOUSE® Deep Vein Thrombosis Compression Device
Regulatory Number: 21 CFR 870.5800
Regulation Name: Sleeve, Limb, Compression
Regulatory Class: Class II
Product Code: JOW
Dated: September 11, 2012
Received: September 19, 2012

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122873

Device Name: VASOPOUSE® IPCS/SQS Deep Vein Thrombosis Compression Device

Indications for Use:

The Caremed Supply Inc. VASOPOUSE® SQS and IPCS Deep Vein Thrombosis (DVT) Compression Devices are intended to increase venous blood flow in at risk patients in order to help prevent deep vein thrombosis.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122873